



Docket No. VIP-0004

1631  
#20  
7-1-03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Kurt Hertogs et al.  
Serial No. : 09/580,491 Art Unit : 1631  
Filed : May 30, 2003 Examiner : Borin, Michael L.  
Title : **NEW MUTATIONAL PROFILES IN HIV-1 PROTEASE AND  
REVERSE TRANSCRIPTASE CORRELATED WITH  
PHENOTYPIC DRUG RESISTANCE**

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Alexandria, VA 22313-1450 on

June 23, 2003  
\_\_\_\_\_  
(Date of Deposit)

Todd F. Volyn  
\_\_\_\_\_  
(Name of applicant, assignee, or Registered Representative)

Todd F. Volyn  
\_\_\_\_\_  
(Signature)

June 23, 2003  
\_\_\_\_\_  
(Date of Signature)

Commissioner For Patents  
Alexandria, VA 22313-1450

Dear Sir:

**RESPONSE TO OFFICE ACTION**

This communication is responsive to the Office Action of May 23, 2003 that relates to  
the application identified above.

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The Examiner maintains that Applicants have failed to respond to his rejection for lack of enablement issued in the Office Action of December 23, 2002. As noted in the response of March 24, 2003, Applicants responded to the 112 first paragraph rejection dated December 4, 2001 on March 1, 2002. On March 4, 2002, the Examiner issued a Final Rejection and stated that: "Any rejections not reiterated have been withdrawn." The enablement rejection of December 4, 2001 was not reiterated and therefore was withdrawn. As there is no new basis for the rejection and no new art cited, the finding of the previous Examiner should stand. MPEP 706.04.

Apparently, the Examiner does not accept this argument. For the purpose of expediting prosecution, Applicants traverse the Examiner's repeated rejection for the following reasons.

Applicants note that the Examiner has misunderstood the description of the correlation of the mutations that appears at page 25 as he asserts that Applicants refer only to Table 1 when discussing 88T. The context of the paragraph make it clear that the discussion directed to 88T refers to Table 2. Note the construction of the description at this point. First, it points out that a single mutation or a combination in Table 1 may confer resistance to a class of drugs. Applicants go on to preface their listing of a few such cases with the phrase, "For example" meaning that these are not the only instances in which such correlations can be made. They then go on to state that "*Likewise*, the protease mutation at 88T confers resistance to nelfinavir, while the combination of protease mutations, 33F + 90M confer resistance to amprenavir." (page 25, line 7, emphasis added). Since the mutations at 88T and 33F+90M appear only in Table 2, clearly one must read this to mean that the mutations in this Table can be used to correlate classes of drugs to mutations just as they were with the mutations listed in Table 1. This is standard grammatical construction. Moreover, this passage illustrates how one correlates resistance to a class of drugs based on certain mutations and concludes that 88T is indicative of PI resistance not merely resistance to nelfinavir. Table 2 and page 25, line 9.

Further, it is worth noting that to comply with 35 USC § 112, first paragraph one must only show how to make and use the invention. Applicants have done just that. For example, at page 29, line 2 it is noted that one method of using the correlations is to load them into a database for retrieving such data and then prescribing a course of therapy based on them. In

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line 9 of the same page Applicants note that this is readily done by insertion of the correlation into an existing assay system as described, the VircoGEN system. Both genotypic and phenotypic analysis of viral mutations are well known, the system for using the data generated in them is known (e.g., the VircoGEN system), and the method of using the system is known. The specification provided the correlation between PI resistance and 88T so there is nothing further that needs to be provided to teach one of ordinary skill in the art how to carry out the invention.

Since the instant application shows a correlation between 88T and PI resistance and shows how one establishes that correlation and uses it according to methods known to those of ordinary skill in the art, 35 USC § 112 is satisfied and this rejection is overcome. Accordingly, allowance of the claims is respectfully solicited.

Respectfully submitted,

By: Todd F. Volyn  
Todd F. Volyn  
Reg. No. 37,463

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(732) 524-6202  
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